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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127

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EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	PAPER NUMBER
1734	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,223	PACETTI ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Established State of the Stent Coating Art

The text concerning the established state of the stent coating art is not included in this action but can be found in the previous Office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-7, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view of Hart (US 6,183,503), Helfrich (US 5,308,338) and Scanlon et al (US 2,845,346).

Jendersee et al teach a stent delivery device (i.e., catheter) or workholder for supporting the stent, the device comprising a tubular support or third element (36) for supporting the stent, a first cuff or retaining element (54) configured to contact one end of the stent and a second cuff retaining element (54) to make contact with another side of the stent whereby the retaining elements can be made from any implantable material from stainless steel to polymers (see col. 7, lines 34-54). Jendersee et al are silent concerning 1) the cuffs or retaining elements being of a shape such that the third element does not contact the stent and 2) the first and/or second element having a porosity to the extent of a closed pore system. However, it was known in the medical art, at the time the invention was made, to provide a tubular support or third element having first and second end retaining elements of a shape to prevent the tubular support or third element from contacting the stent as evidenced by Hart et al (see col. 4, lines 9-18). Also, it was known in the medical art, at the time the invention was made, to provide a catheter with cuffs made from

porous implantable materials including polymers to sintered metal and ceramics as evidenced by Helfrich (see col. 4, lines 31-39). It was further known in the sintered metal composite art, to enable sintered metal bodies to be made of a closed pore construction as evidenced by Scanlon et al (see col. 1, lines 1 5-23). In light of the teachings of Jendersee et al that any implantable material can be used to make the retaining elements, the teachings of Hart et al that the retaining elements can be of a shape to prevent contact of the stent with the tubular support, the teaching of Helfrich with respect to catheters having cuffs made from porous material (i.e., sintered metal), and the teaching of Scanlon et al, that sintered metal while porous, can be made to have a closed pore system, it would have been obvious to one of ordinary skill in the art to make the retaining elements of an appropriate shape to prevent contact of the stent with the support to facilitate removal of the stent from the workholder when inserted into the body and to make the retaining elements of an appropriate porosity to the extent of a non-porous (i.e., closed-pore) implantable material so as to retain the stent on the workholder during processing before insertion into the body. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining elements, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without a positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

With respect to the pore size, it is within the level of ordinary skill in the art to determine, via routine experimentation, the appropriate pore size including diameter of the material used to make the retaining elements.

Claims 27-32 art rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view of Hart et al (US 6,183,503) and Helfrich (US 5,308,338).

Jendersee et al teach a stent delivery device (i.e., catheter) or workholder for supporting the stent, the device comprising a tubular support or third element (36) for supporting the stent, a first cuff or retaining element (54) configured to contact one end of the stent and a second cuff retaining element (54) to make contact with another side of the stent whereby the retaining elements can be made from any implantable material from stainless steel to polymers (see col. 7, lines 34-54). Jendersee et al are silent concerning 1) the cuffs or retaining elements being of a shape such that the third element does not contact the stent and 2) the first and/or second retaining element having a porous layer thereon capable of absorbing or at least partially absorbing a fluid. However, it was known in the medical art, at the time the invention was made, to provide a tubular support or third element having first and second end retaining elements of a shape to prevent the tubular support or third element from contacting the stent as evidenced by Hart et al (see col. 4, lines 9-18). It was also known in the medical art, at the time the invention was made, to provide a catheter with cuffs made from porous implantable materials (i.e., polymers to sintered metal and ceramics) to promote ingrowth of tissue as evidenced by Helfrich (see col. 4, lines 31-39). In light of the teachings of Hart et al, it would have been obvious to one of ordinary skill in the art to provide the retaining elements of an appropriate shape to prevent

contact of the stent with the tubular support in order to facilitate removal of the stent from the workholder upon insertion into the body due to less contact area of the stent with the workholder body. Also, it would have been obvious to one of ordinary skill in the art to make the cuffs or retaining elements of a porous layer material as taught by Helfrich in the device of Jendersee et al in order to enable the absorption or retention of fluid when the stent is pretreated or enable tissue growth when device is implanted. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining elements, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without the positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

Claims 1, 2, 4-6, and 25-32 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Frisch (US 4,906,423) in view of Hart et al (US 6,183,503).

Frisch teaches a support mandrel for manufacturing a prosthetic device or stent comprising a shaped member configured to support a stent, the member having a plurality of pores disposed on a surface thereof wherein the pores are capable of receiving a coating substance during a coating process wherein the pores can include open to closed cells (see col. 3, lines 60- 62). Even though Frisch recognizes that at least some of the cells should be open (col.

3, lines. 60-65, Frisch remains to include in the range of cell construction, closed cells as would be determined via routine experimentation in accordance with the foam material employed. Frisch does not recognize the mandrel comprising a first end element and a second end element to contact both sides of the stent, however, the use of a mandrel or work support of a dumbbell shape having end elements capable of contacting opposite sides of stent such that the stent does not contact the mandrel between the first and second end elements was known in the medical art as evidenced by Hart et al (see Fig. 3). It would have been within the purview of one skilled in the art to shape the porous mandrel as taught by Frisch in a dumbbell form as taught by Hart et al in order to retain or secure the stent in place between the two end elements of the mandrel as the stent is processed. One of ordinary skill in the art would expect that the dumbbell shaping of the end retaining elements would facilitate removal of the stent from the workholder upon insertion into the body due to less contact area of the stent with the work support body.

Applicants' use of the term "comprising" is deemed open ended language which would not exclude the teachings of Frisch to the use of a few open cells in combination with a closed pore system.

With respect to claim 2, even though Frisch teaches that the pore size and density of the porous surface is controlled by cell size and density of foam material employed (see col. 3, lines 67+ to col. 4, lines 1-22), Frisch is silent concerning the pore diameter of .2 to 50 microns. However, one of ordinary skill in the art would determine via routine experimentation the appropriate foam material to use having a desired pore diameter in accordance with the medical device being produced and the amount of coating material sought to be absorbed on the supported mandrel.

With respect to claims 4-6, 25, and 26, see Frisch, col. 3, lines 60 to col. 4, lines 1-30.

With respect to claims 31 and 32, Applicants' recitation of the absorbent material to partially absorb coating material is acknowledged, however, the device as defined by the combination above would still at least partially absorb coating material based upon the type of polymeric foam material used to make the mandrel.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

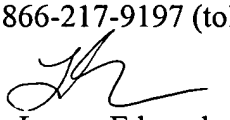
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards
Primary Examiner
Art Unit 1734

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March 16, 2006